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NEWS IN BRIEF

Top product sales forecasts for 2018

The top-selling drugs of 2018 are set to be a mix of old-timers and newcomers, shows global consensus sales forecast data from EvaluatePharma.

The top five products on this forecast list are repeat bestsellers, and AbbVie's adalimumab held the top slot in both 2016 and 2017. Several of these top earners are likely to come under pressure in upcoming years from biosimilar launches (*Nat. Rev. Drug Discov.* **16**, 152–154; 2017). But, analysts are optimistic that AbbVie has eked out a few more years of security for its prize antibody, because the company settled last year with Amgen to delay the US launch of an approved biosimilar version of adalimumab until 2023.

A few newcomers, meanwhile, are quickly climbing up the rankings. Most notably, Merck & Co.'s pembrolizumab and Bristol-Myers Squibb's nivolumab are set to make first appearances on the top-ten list. These PD1-blocking checkpoint inhibitors were first approved for melanoma in 2014 and have since gained approval for other cancers. Sales of Merck's pembrolizumab lagged behind nivolumab in 2016 and 2017, but the antibody is positioned to overtake its competitor in part because of encouraging efficacy in first-line non-small-cell lung cancer.

Promising clinical data and high sales forecasts for these PD1 blockers have prompted other companies to invest heavily in immuno-oncology drug development. Several other PD1- or PDL1-targeted drugs have since entered the market, with more in late-stage development (*Nat. Rev. Drug Discov.* **15**, 235–247; 2016).

Asher Mullard

Product	Company	2018 global sales forecast (US$ billions)
Adalimumab (Humira)	AbbVie	19.7
Lenalidomide (Revlimid)	Celgene	9.2
Bevacizumab (Avastin)	Roche	6.7
Rituximab (Rituxan)	Roche	6.6
Trastuzumab (Herceptin)	Roche	6.6
Pembrolizumab (Keytruda)	Merck & Co.	6.0
Apixaban (Eliquis)	Bristol-Myers Squibb/Pfizer	5.9
Pneumococcal 13-valent vaccine (Prevnar 13)	Pfizer	5.7
Pregabalin (Lyrica)	Pfizer	5.2
Nivolumab (Opdivo)	Bristol-Myers Squibb	5.1

Source: EvaluatePharma, December 2017.

Pfizer exits neuroscience

Pfizer is pulling out of neuroscience drug discovery and early development, and cutting 300 positions in its neuroscience division.

Prior to the announcement, the company had eight neuroscience products in phase I and phase II trials. These consisted of four clinical programmes in Alzheimer disease, as well as candidates for Parkinson disease, epilepsy, schizophrenia and cognitive disorder. Alzheimer drug development efforts are especially fraught, with an estimated 99.6% failure rate. Speaking at the J.P. Morgan Healthcare conference in January, Pfizer's head of R&D Mikael Dolsten defended the move as a means "to focus and reallocate our resources into the other five areas where we think we can give the most value mid-term to shareholders and patients."

But Morgan Sheng, vice president of Neuroscience at Genentech, is optimistic that new neuroscience therapeutics are on the horizon. "I don't see a mass exodus of big pharma and biotech out of neuroscience. Quite the opposite, the field is becoming increasingly competitive, especially in neurodegenerative disorders, multiple sclerosis, pain and rare diseases of the nervous system," he says. Genetic analyses in particular are helping to identify the molecular underpinnings of neural diseases and are pointing to new CNS targets in these indications, he adds (see page 88).

Recent deal-making activity bolsters Sheng's position. Takeda Pharmaceuticals partnered with Denali Therapeutics in January in a deal that could be worth up to US$1.2 billion to collaborate on three programmes for Alzheimer disease and other neurodegenerative diseases. In December the neuroscience-focused Denali also pulled off the biggest biotech initial public offering of 2017, raising $250 million.

Johnson & Johnson also announced four neuroscience collaborations in January, including projects looking at gene therapy for Alzheimer disease and the role of the microbiome in sleep disorders.

Asher Mullard

EMA recommended 35 new drugs in 2017

The European Medicines Agency (EMA) recommended approval for 35 new therapeutic agents last year, compared with 27 in 2016 and 39 in 2015.

The EMA's count includes small molecules, antibodies, biologics, blood products, cellular therapies and vaccines. As such, it cannot be compared directly with approvals from the FDA's Center for Drug Evaluation and Research (CDER), which reviews only small molecules and some types of biologic. (The FDA's CDER had a standout year for approvals in 2017; see page 81.) There is nevertheless considerable overlap in the new drug lists, including approvals for blockbuster contenders such as Regeneron and Sanofi's interleukin-4 receptor subunit-α antagonist dupilumab for atopic dermatitis, Roche's anti-CD20 ocrelizumab for multiple sclerosis and Novo Nordisk's GLP1 receptor agonist semaglutide for type 2 diabetes.

The EMA gave green lights to several drugs that have not yet been approved in the US. For example, it recommended Ultragenyx's anti-FGF23 antibody burosumab for X-linked hypophosphataemia. This antibody is currently under review at the FDA for possible approval by May. The EMA also gave a thumbs up to Dompé's recombinant human nerve growth factor oxervate, for neurotrophic keratitis. Dompé has initiated a rolling submission to get FDA approval of this drug.

The EMA also recommended approval for TiGenix and Takeda's darvadstrocel, for complex perianal fistulas in patients with Crohn's disease. This product is the first donor-derived 'off-the-shelf' stem cell therapy to gain approval in the European Union. The sponsors have yet to disclose a US filing timeline for this product.

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